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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,980	03/13/2001	Peter Andersen	670001-2002.4	9361

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EXAMINER
SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/804,980	ANDERSEN ET AL	
	Examiner	Art Unit	
	Rodney P. Swartz, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 9-11,26, 28, drawn to polypeptide, classified in class 424, subclass 248.1.

II. Claims 7, 22, 29, drawn to method of diagnosis using polypeptide, classified in class 435, subclass 7.1.

III. Claims 8, 23, 27, drawn to method of immunization using polypeptide, classified in class 424, subclass 9.1.

IV. Claims 12-20, 26, 28, drawn to DNA, vector, and transformed cell, classified in class 536, subclass 23.7.

V. Claim 21, drawn to a method of using DNA to make polypeptide, classified in class 424, subclass 93.2.

VI. Claim 29, drawn to method of diagnosis using DNA, classified in class 536, subclass 24.32.

VII. Claim 27, drawn to method of immunization using DNA, classified in class 514, subclass 44.

VIII. Claims 24, 25, drawn to antibody, classified in class 424, subclass 139.1.

IX. Claim 29, drawn to method of diagnosis using antibody, classified in class 424, subclass 7.1.

Claim 26 is a pharmaceutical composition comprising polypeptide **or** DNA **or** transformed cell. Claim 27 is a method of immunization using polypeptide **or** DNA **or** transformed cell. Claim 28 is a composition comprising polypeptide **or** DNA **or** transformed cell. Claim 29 is a method of diagnosis using polypeptide **or** DNA **or** antibody. Therefore, claims 26, 27, 28, and 29 have been included into multiple inventions where appropriate. However, election of **a single** invention which includes either claim 26, 27, 28, or 29 necessitates that claim 26, 27, 28, or 29 is directed **only** to the elected invention. Appropriate amendment of claim 26, 27, 28, or 29 is required upon election to **recite only the elected invention**.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV-IX are drawn to structurally and functionally distinct molecules. Invention I is drawn to polypeptide while Inventions IV-VII are drawn to nucleic acids and Inventions VIII-IX are drawn to antibodies.

Invention I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Invention I can be used to immunize a host against infection with mycobacteria.

Invention I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of Invention I can be used for *in vitro* diagnosis of infection with mycobacteria.

Inventions II and IV-IX are drawn to structurally and functionally distinct molecules. Invention II is drawn to polypeptide while Inventions IV-VII are drawn to nucleic acids and Inventions VIII-IX are drawn to antibodies.

Invention II and III are drawn to patently distinct methods which use different steps and have different results. Invention II is a method of diagnosis while Invention III is a method of immunization.

Inventions III and IV-IX are drawn to structurally and functionally distinct molecules. Invention III is drawn to polypeptide while Inventions IV-VII are drawn to nucleic acids and Inventions VIII-IX are drawn to antibodies.

Inventions IV and VIII-IX are drawn to structurally and functionally distinct molecules. Invention IV is drawn to nucleic acids and Inventions VIII-IX are drawn to antibodies.

Invention IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA, vector and transformed cells of Invention IV can be used to immunize hosts against infection with mycobacteria.

Invention IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA, vector and transformed cells of Invention IV can be used to immunize hosts against infection with mycobacteria.

Invention IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA, vector and transformed cells of Invention IV can be used to produce polypeptide.

Inventions V and VIII-IX are drawn to structurally and functionally distinct molecules. Invention V is drawn to nucleic acids and Inventions VIII-IX are drawn to antibodies.

Invention V and VI are drawn to patently distinct methods which use different steps and have different results. Invention V is a method of making polypeptide while Invention VI is a method of diagnosis.

Invention V and VII are drawn to patently distinct methods which use different steps and have different results. Invention V is a method of making polypeptide while Invention VII is a method of immunization.

Inventions VI and VIII-IX are drawn to structurally and functionally distinct molecules. Invention VI is drawn to nucleic acids and Inventions VIII-IX are drawn to antibodies.

Invention VI and VII are drawn to patently distinct methods which use different steps and have different results. Invention VI is a method of diagnosis while Invention VII is a method of immunization.

Inventions VII and VIII-IX are drawn to structurally and functionally distinct molecules. Invention VII is drawn to nucleic acids and Inventions VIII-IX are drawn to antibodies.

Inventions VIII and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibodies of Invention VIII can be used for passive immunization of a subject against infection with mycobacterium.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and because while the searches may overlap, the searches are not coextensive, restriction for examination purposes as indicated is proper.

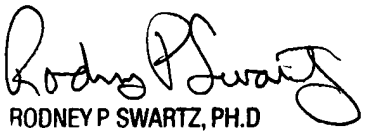
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

March 11, 2003